

Applicants affirm their election of the claims of Group I. These claims have now been rewritten as new claims 75 - 94. Claims 75 - 83 correspond to claims 44 - 52 and draw support from the specification in the same manner. Claims 84 - 90 correspond to claims 60 - 66 and draw support from the specification in the same manner. Claims 91 - 94 correspond to claims 68, 69, 73 and 74 respectively and draw support from the specification in the same manner.

Applicants submit herewith a substitute specification in accordance with the Examiner's request for the same at paragraph 4 of the Official Action. The substitute specification includes the amendments made by Applicants' Amendment dated January 28, 1999 pertaining to the sequence identifiers. The substitute specification also contains amendments to correct the informalities noted by the Examiner paragraphs 4(b) - 4(i) of the Official Action and to correct other typographic and clerical errors. In addition to a clean copy of the substitute specification, Applicants submit herewith a specification marked with underlining and bracketing to show where the corrections have been made. An Abstract of the Disclosure has been added to the specification.

The undersigned hereby states on behalf of Applicants that no new matter has been introduced into the substitute specification.

The claims have been rewritten to remove the bases for the Examiner's rejections at paragraphs 7 - 16 of the Official Action. In particular, the claims directed to the antigen recite an isolated antigen so as to remove the basis for the rejection under 35 USC 101. Moreover, the allegedly objectionable term "putative protective" does not appear in the claims as rewritten.

Nevertheless, the claims include specific requirements as to the timing and location of immune cell harvest from a mammal. These specific requirements of the claimed method provide for a high likelihood of identifying antigens which are protective.

It is respectfully submitted that the claims as rewritten are sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph. In this connection, the claims under examination no longer depend from nonelected claims. Moreover, the language of the claims respectively reciting at least one antibody and at least one antigen has been made consistent and reflects the understanding of those of skill in the art that the antigenic matter which binds to the claimed at least one antibody will not be homogeneous in composition. Furthermore, the objectionable spaces do not appear in the claims as rewritten and the claims refer to the recited sequences using the corresponding SEQ ID NOs described in the specification.

With respect to the rejection under USC 112, first paragraph appearing at paragraph 11 of the Official Action, the applicable claims now recite that the claimed antibody is produced from antibody producing cells. This amendment removes the basis for the rejection at paragraph 11 of the Official Action.

With respect to the rejection under 35 USC 112, first paragraph appearing at paragraph 12 of the Official Action, the claims as rewritten are directed to mutants, derivatives or fragments that stimulate production of the recited antibodies in a mammal. It would require no more than routine experimentation using techniques described in the specification and well known to those of skill in the art to identify efficacious mutants, derivatives and fragments as claimed. For

example, the generation of specific point mutants is routine, and subsequent testing for protective antigenicity would not require undue experimentation. Furthermore, the claimed invention clearly provides a substantial conceptual leap over the prior art, and Applicants should not be deprived of protection for mere mechanical equivalents in the form of mutants, derivatives or fragments.

With respect to the rejection under 35 USC 112, first paragraph appearing at paragraph 13 of the Official Action, Applicants respectfully note that the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention in the specification. The claims as rewritten are limited to antigens that are effective in mammals and the specification provides a presumptively enabling disclosure in this respect (see, for example, specification at page 7, lines 10 - 11). Under the provisions of MPEP Section 2164.04, the specification disclosure must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein. In the present case, the Examiner has not offered any suitable explanation as to why the claimed invention would not work with mammals other than pigs. In the absence of such explanation, it is respectfully submitted that Examiner has not set forth even a *prima facie* case for alleged lack of enablement (see MPEP Section 2164.04).

In any event, Applicants note that the immunology and pathology of *Mycoplasma* infection is similar across all mammals, in that infection occurs on mucosal surfaces giving rise to lesions at those sites (i.e., genitourinary tract, and respiratory surfaces). See, "Medical Microbiology" Chapter 52 (2nd Edition), Editor Samuel Baron (1988) Addison-Wesley,

California (copy submitted herewith). Accordingly, the skilled person could easily practice the claimed invention on any mammal without undue experimentation. With specific reference to the Examiner's comments regarding treatment methodology and dosages in subjects other than pigs, Applicants respectfully submit that the establishment of an optimum dosage, route of administration, etc., would not require anything other than routine experimentation wherein the methodology and dosages provided in the specification for pigs could be used as a guide.

The Examiner had rejected certain claims under 35 USC 102(b) as allegedly being anticipated by Faulds et al. Applicants respectfully traverse this rejection.

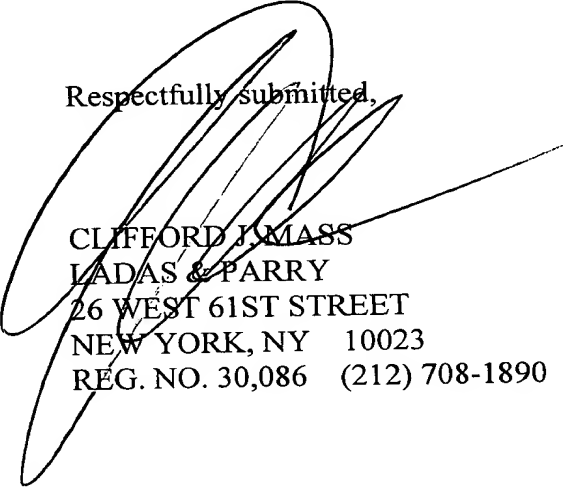
The Examiner has noted that Faulds et al teach a protective antigen having an approximate molecular weight of 72 - 75 kilodaltons. This 74.5 kDa component has a sequence of amino acid residues in its amino terminus which consists of the amino acids described in Faulds et al at column 6, lines 17 - 19. By contrast, the applicable claims as rewritten recite that the claimed antigens having a molecular weight within the 72 - 75 kilodalton range have an amino terminus comprising a different amino acid sequence. Accordingly, Faulds et al cannot be said to anticipate the invention as now claimed.

It is noted that the Examiner has attempted to shift the burden of proof to Applicants by contending that "in the absence of evidence to the contrary", Faulds et al would comprise the recited sequences. Applicants respectfully submit that where, as here, the reference is silent about an asserted inherent characteristic, the U.S. Patent and Trademark Office has the burden of showing that the missing descriptive matter is necessarily present in the reference and that it

would be so recognized by persons of ordinary skill in the art (see MPEP Section 2131.01 at subparagraph III). If such burden is not met, the rejection should be withdrawn.

In view of the above, all rejections and objections of record are believed to have been successfully traversed and the application is believed to be in allowable form. An early Notice of Allowability is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



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